K042503

OCT 1 - 2004

2. 510(k) SUMMARY of Safety and Effectiveness

As required by Section 807.92(c)

2.1 Submitter: [807.92 (a)(1)]

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2.2 Contact Person: [807.92 (a)(1)]

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2.3 Date Summary Prepared: [807.92 (a)(1)]

September 8, 2004

2.4 Device Names: [807.92 (a)(2)]

Proprietary	CliP® Piston MVP
Common	MVP Piston
Classification	Replacement, Ossicular Prosthesis, Total
Product Code	77 ETA
Regulation #	CFR 874.3495

2.5 Reason for Submission:

Change in design and combination of design features of previously cleared devices

2.6 Intended Use: [807.92 (a)(5)]

Bridging the stapes and the incus in cases of otosclerosis, specifically for malleovestibulopexy

2.7 Modification and Combination of Existing Device Components: [807.92 (a)(3)]

K 002221 K-Piston Titanium Stapedial Prosthesis (Partial and Total)
Cleared 08/09/2000 +

K 021479 CliP® àWengen Stapedial Piston
Cleared 05/21/2002

2.8 Device Description: [807.92(a)(4)+(6)]

The all-titanium prosthesis consists of an undulated, self-retaining, two-limbed clip[1] that is laser-welded to a rectangular shaft which is connected with a conventional KURZ piston shaft by means of a unique ball joint.[2]

2.9 Reasons for Device Modification: [807.92 (d)]

To facilitate and standardize intraoperative handling, reduce risks of patient trauma, and improve post-operative sound transmission in the affected ear.

Traditionally, common loop pistons had to be bent to an almost right angle to permit crimping to the malleus handle. With the piston articulation, no implant manipulation is required. The surgeon can bend the shaft to precisely match the patient's physiological condition.

By replacing the titanium band loop[3] with a modified àWengen clip[4] for fastening the prosthesis to the malleus handle, the clinically proven advantages of this method of attachment are added to the new device:

(1) reduction of tissue necrosis by improving vascular circulation;
(2) standardization and significant shortening of surgical procedure by means of 'click-on' mechanism for attachment to the malleus handle;
(3) elimination of need for instruments and crimping to reduce the potential risks connected therewith;
(4) improvement of audiological results as a result of gentle clip-on attachment to malleus handle.

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[1] A modification of the CliP® àWengen
[2] See magnified illustration and engineering drawing, pp. 4-8 to 4-9
[3] K 002221
[4] K 021479

2.10 Industry Standards: [807.92 (d)]

KURZ certifies compliance with all appropriate industry standards and the validation of methods and processes covered by these standards.

2.11 MRI Environment: [807.92 (d)]

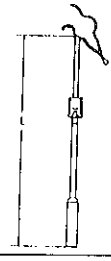
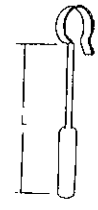
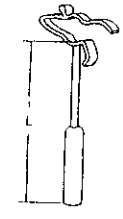
Testing in a 3.0 Tesla nuclear magnetic resonance (NMR) tomograph has revealed no implant movement and no adverse tissue effects attributable to MRI-generated heating.

2.12 Information Bearing on the Safety and Effectiveness: [807.92 (b)(3)]

Like some lengths of the K-Piston Titanium Stapedial Prosthesis, the CliP® Piston MVP is used for bridging the stapes and incus in cases of otosclerosis in malleovesti-bulopexy procedures. The ball joint eliminates implant bending. The click-on mechanism and the self-retaining clip design of the modified KURZ CliP® àWengen shorten the attachment procedure to the malleus handle, minimize the risks connected with instrument manipulation and, by improving vascular circulation, reduce the risk of tissue necrosis. The gentle attachment to the malleus handle along the axis of mechanical sound transmission is expected to result in equal if not better audiological post-operative hearing gain. There are no additional characteristics known that should adversely affect the safety and effectiveness of these implants.

The results of design validation raise no new issues of safety and effectiveness.

2.13 COMPARISON of DESIGN + SAFETY and EFFECTIVENESS

Device	CliP® Piston MVP	Titanium K-Piston K 002221	CliP àWengen K 021479 (Only for Comparison of CliP)
Catalog #	1006 711-13 0.4 mm 1006 761-63 0.6 mm	1006 103 – 1006 170	1006 805 – 1006 861
Intended Use	Bridging the stapes and incus in cases of otosclerosis, specifically defects of the ossicular chain between manubrium mallei and vestibulum (malleovestibulopexy)	1. Bridging the stapes in cases of otosclerosis 2. Bridging the stapes and incus in cases of otosclerosis, specifically defects of the ossicular chain between manubrium mallei and vestibulum (malleovesti-bulopexy)	
Design	Standard KURZ Piston connected to modified àWengen Clip w/ball joint articulation 	Standard KURZ Piston gradually tapering towards band loop 	Standard KURZ Piston with áWengen Clip 
# of Sizes	6 (3 for each Ø)	28 (14 for each Ø)	
Device Lengths	**5.75 – 6.25 mm** (0.25 mm intervals)	**3.50 – 6.00 mm** (0.25 mm intervals) **6.00 – 10.00 mm** (1.00 mm intervals)	
Piston Ø	0.4 + 0.6 mm	0.4 + 0.6 mm	
Attachment to Malleus Handle	Modified àWengen Clip	(Titanium band loop)	àWengen Clip
Implant Manipulation	**None**: Articulation permits precise piston bending to accommodate surgical site	Surgeon bends piston to almost 90° for attachment to malleus handle	
Material	Titanium ASTM F67	Titanium ASTM F67	Titanium ASTM F67
Single Use	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Design Comparison - Implant	An open clip (**modified àWengen**) is attached to a 0.2 mm rectangular shaft. A novel ball joint connection to the standard KURZ piston (0.4 + 0.6 mm) permits precise intra-operative 'bending' without implant manipulation to exactly accom-modate patient's physiological require-ments.	A laterally displaced band loop is attached to a 0.2 mm shaft that is seamlessly laserwelded to the piston (0.4 + 0.6 mm). Piston requires almost 90° bending for attachment to malleus handle.	An open clip (**àWengen**) is attached to a 0.2 mm shaft that is seamlessly laserwelded to the piston stem (0.4 + 0.6 mm)
Design Comparision - CliP®	- The protuberance for grasping CliP has been moved to end - Limb undulation has been changed to conform to more oval circumference of malleus handle - CliP limb opening and length was slightly adjusted to assure precise fit around malleus handle		- The protuberance for grasping CliP is located on top of upper limb - Limb undulation has been designed for exact fit around long incudal process
Custom Accessories	**KURZ Meter** Cat. # 8000 106 (to determine proper device length)	Identical	

Safety & Effectiveness of Design Changes [807.92 (b)(1)]	The novel ball joint piston articulation eliminates implant bending. Attachment to the malleus handle with the previously cleared tensile clip-on mechanism[5] shortens surgical procedure, reduces risk of tissue necrosis by improving vascular circulation, reduces risk of implant dislocation with high degree of certainty, potentially improves long-term hearing gain with appropriate physiological conditions, and significantly reduces risks of patient trauma. Clinical test results confirm the safety and effectiveness of this design. There are no known characteristics that would introduce adverse effects.		

9/9/2004 11:37 AM

Date 09/09/04

Signature _____

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Uwe Steinhardt
Technical Director

[5] CliP® Piston àWengen K 021479

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

HEINZ KURZ GMBH MEDIZINTECHNIK
c/o Business Support International
Amstel 320-I
Amsterdam, Netherlands 1017AP
Attn: Dagmar Mäser

Re: K042503
Trade/Device Name: KURZ CLIP® Piston MVP
Regulation Number: 21 CFR 874.3495
Regulation Name: Total Ossicular Replacement Prosthesis
Regulatory Class: Class II
Product Code: ETA
Dated: September 14, 2004
Received: September 15, 2004

Dear Ms. Mäser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042503

Device Name: **CLiP® Piston MVP**

Indications for Use: Bridging the stapes and incus in cases of otosclerosis and defects of the ossicular chain between manubrium mallei and vestibulum (malleovestibulopexy)

9/9/2004 1:57 PM

Prescription Use ✓ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K042503